DETAILED ACTION

Status of Application

Restriction Response

1. Applicant's election without traverse of Group I (claims 1-11 and 15-17) in the reply filed on 4/9/08 is acknowledged.

2. Claims 12-14 and 18-20 are withdrawn from consideration.

3. Claims 1-11 and 15-17 are included in the prosecution.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 2/11/05 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Drawings

6. Applicant is required to submit drawings separately, not as part of the specification. Please see MPEP, 37 CFR § 1.84 for Standards for drawings.

7. It is recommended that Applicant includes a section titled "Brief Description of Drawings" in the Specification. Please see MPEP, 608.01(a) for the placement of this section in the Specification.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-4, 6-11 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanden Berghe (EP 1 110 909 A1) in view of Bronder (US 5,922,360).

The claimed invention is a method for the preparation of a silicic acid comprising extrudate. The method comprises the steps of: i) forming stabilized silicic acid, by hydrolysing a silicon compound into orthosilicic acid and/or oligomers in the presence of a stabilizing agent, which is a quaternary ammonium compound, or an amino-acid, or an amino acid source or combinations thereof; ii) mixing of the stabilized silicic acid with a carrier in an amount up to the loading capacity of the carrier for silicic acid; and iii) extruding the resulting mixture thereby forming the extrudate.

Vanden Berghe teaches a method for preparing ortho silicic acid where an acid hydrolysable silicon compound is hydrolysed in an acid solution in the presence of a solvent agent (Page 2, [0003]). “The formed ortho silicic acid stabilized by the solvent agent, may be stabilized further by contacting the ortho silicic acid with a particulate carrier” (Page 2, [0008]). The solid carrier or combination of carriers include cellulose or derivatives such as microcrystalline cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, carboxymethylcellulose, cellulose gum, pectin, alginates, sugars or

sugar alcohols, lactose, peptides and polypeptides, starch and derivatives (Page 4, [0015]). Example B discloses 65% of carrier (microcrystalline cellulose) that is mixed with 35% of a combination of concentrated ortho silicic acid with solvent (glycerol). Demineralized water is added during continuous mixing to obtain an appropriate quality of the granulated material. The plastic mass is extruded. The extruded strands are spheronized. The resulting pellets are dried to a final water content of lower than 5 %. Typical pellet size is between 800 and 1200 μm (Page 4, [0019]).

Vanden Berghe does not expressly teach the stabilization of orthosilicic acid with a quaternary ammonium compound such as choline chloride.

Bronder teaches a method for preparing a stabilized orthosilicic acid preparation which comprises: i) providing a solution containing a stabilizing agent; ii) dissolving an inorganic silicon compound in the solution containing the stabilizing agent; and iii) hydrolyzing the silicon compound to ortho silicic acid (Col. 1, lines 39-45). Quaternary ammonium compounds are disclosed as stabilizing agents, especially choline which "has been found very suitable, which is further recommended in that it provides the option of the stabilizing agent also forming the solution for the ortho silicic acid, and an inert solvent can therefore be omitted. Another or additional type of stabilizing agent is an amino acid, such as proline or serine" (Col. 1, line 59 to Col. 2, line 6). Bronder teaches that choline may be converted to choline hydrochloride (Col. 2, lines 18-19). Bronder discloses preparations with "3-5% by weight of silicon, 70% by weight of choline hydrochloride and the rest water" (Col. 2, lines 47-51). Formulation example A

discloses 3% by weight silicon in the form of ortho silicic acid, 70% by weight choline hydrochloride, the rest water (Col. 3, lines 47-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of stabilizing ortho silicic acid with a solvent agent and further using a carrier such as microcrystalline cellulose with the ortho silicic acid to extrude, spheronized and dry the resultant pellets, as taught by Vanden Berghe, substitute the solvent with a stabilizer such as a quaternary ammonium compound like choline or an amino acid, as taught by Bronder, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bronder teaches that "if ortho silicic acid is formed in the presence of a stabilizing agent, polycondensation is inhibited and even avoided and, furthermore organic silicon compounds substantially do not occur" (Col. 1, lines 31-35).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of the method of preparing a silicic acid extrudate comprising the step of forming a stabilized silicic acid would have been obvious over the method of preparing a silicic acid extrudate, as taught by Vanden Berghe (Page 4, [0019]). The limitation of stabilizing silicic acid in the presence of a stabilizing agent which is a quaternary ammonium compound or an amino acid would

have been obvious over the quaternary ammonium compound choline and amino acids proline or serine used to stabilize ortho silicic acid, as taught by Bronder (Col. 1, line 59 to Col. 2, line 6). The limitation of mixing the stabilized silicic acid with a carrier would have been obvious over the particulate carrier including cellulose or derivatives such as microcrystalline cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, carboxymethylcellulose, cellulose gum, pectin, alginates, sugars or sugar alcohols, lactose, peptides and polypeptides, starch and derivatives, as taught by Vanden Berghe (Page 2, [0008] and Page 4, [0015]). The limitation of extruding the mixture would have been obvious over the extrusion of the mixture, as taught by Vanden Berghe (Page 4, [0019]).

Regarding instant claim 2, the limitation of orthosilicic acid would have been obvious over the orthosilicic acid taught by Vanden Berghe (Page 2, [0008]).

Regarding instant claims 3 and 15, the limitation of choline chloride as the quaternary ammonium compound would have been obvious over the choline hydrochloride taught by Bronder (Col. 2, lines 1-4).

Regarding instant claims 4 and 16, the limitation of the amino acids such as proline and serine would have been obvious over the amino acid stabilizers such as proline and serine taught by Bronder (Col. 2, lines 5-6).

Regarding instant claim 6, the limitation of 2.5-3.5% by volume silicon, 65-75% by weight choline, and 15-25% by weight water would have been obvious over formulation example A that discloses 3% by weight silicon in the form of ortho silicic

acid, 70% by weight choline hydrochloride, the rest water, as taught by Bronder (Col. 3, lines 47-49).

Regarding instant claim 7, the limitation of the carrier mixed with the stabilized silicic acid in a ratio of 65-50% and 35-50% respectively would have been obvious over 65% of carrier (microcrystalline cellulose) that is mixed with 35% of a combination of concentrated ortho silicic acid with solvent (glycerol) as taught by Vanden Berghe (Page 4, [0019]) in view of the silicic acid stabilized with choline as taught by Bronder (Col. 2, lines 1-4).

Regarding instant claim 8, the carrier would have been obvious over the particulate carrier including cellulose or derivatives such as microcrystalline cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, carboxymethylcellulose, cellulose gum, pectin, alginates, sugars or sugar alcohols, lactose, peptides and polypeptides, starch and derivatives, as taught by Vanden Berghe (Page 2, [0008] and Page 4, [0015]).

Regarding instant claim 9, the limitation of microcrystalline cellulose would have been obvious over the microcrystalline cellulose taught by Vanden Berghe (Page 4, [0015]). The limitation of the loading capacity for stabilized silicic acid $< 50\%$ would have been obvious over the 35% of a combination of concentrated ortho silicic acid with solvent (glycerol) as taught by Vanden Berghe (Page 4, [0019]).

Regarding instant claim 10, the limitation of spheronizing the extrudate into particles would have been obvious over spheronizing extruded strands, as taught by Vanden Berghe (Page 4, [0019]).

Regarding instant claim 11, the limitation of drying the particles and having a particles size between about 800 to about 1200 μm would have been obvious over drying the resulting pellets and the typical pellet size that is between 800 and 1200 μm, as taught by Vanden Berghe (Page 4, [0019]).

10. Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanden Berghe (EP 1 110 909 A1) in view of Bronder (US 5,922,360) and further in view of Seguin et al. (US 6,335,457).

The teachings of Vanden Berghe and Bronder are stated above.

Vanden Berghe and Bronder do not expressly teach a polypeptide or a protein hydrolysate as an amino acid source.

Seguin teaches "complexing ortho silicic acid with a polypeptide which acts as a stabilizer by forming hydrogen bonds with orthosilicic acid. This prevents the formation of siloxane bonds and orthosilicic acid polymerisation" (Col. 2, lines 50-54). Seguin teaches that the ortho silicic acid complexed with a polypeptide shows excellent stability of the concentrated solid form, and is able remain stable during its transit in the gastrointestinal tract, and this despite the existence of different physiological pH favouring its polymerisation (Col. 2, lines 59-63). Example 1 discloses the preparation of an orthosilicic acid powder with hydrolyzed gelatin and Example 2 discloses the preparation of an orthosilicic acid powder with a wheat protein hydrolysate (Col. 3, line 60 to Col. 4, line 26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of stabilizing ortho silicic acid with a solvent

agent and further using a carrier such as microcrystalline cellulose with the ortho silicic acid to extrude, spheronized and dry the resultant pellets, as taught by Vanden Berghe, substitute the solvent with a stabilizer such as a quaternary ammonium compound like choline or an amino acid, as taught by Bronder, further combine it with complexing silicic acid and a polypeptide stabilizing agent, as taught by Seguin, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Seguin teaches that the polypeptide stabilizer forms hydrogen bonds with orthosilicic acid and this prevents the formation of siloxane bonds and orthosilicic acid polymerisation (Col. 2, lines 50-54).

Regarding instant claims 5 and 17, the limitation of polypeptide or protein hydrolysate as the amino acid source would have been obvious over the polypeptide stabilizer (Col. 2, lines 5-6) and the hydrolyzed gelatin and wheat protein hydrolysate (Col. 3, line 60 to Col. 4, line 26) taught by Seguin.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
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